III SUMMARY OF INFORMATION REGARDING SAFETY AND EFFECTIVENESS

Van Oostveen Medical B.V.
510(k): Surgeon's gloves

	510(k) SUMMARY Prepared August 2002	
TRADE NAME	ROMED latex surgeon's gloves, sterile, powdered	
GENERIC NAME	Surgeon's gloves	
CLASSIFICATION	Class I (21 CFR 878.4460)	
SUBMITTED BY	Van Oostveen Medical B.V. Herenweg 269 3648 CH WILNIS The Netherlands	CONTACT: Mrs. M.J. van Oostveen Mrs. Y.A. Zwaartman Tel.: 00 31 297 282101 Fax: 00 31 297 288316
PREDICATE DEVICES	K014278 Brightway Gloves, India K021065 Primus Gloves Private Ltd., India	
DEVICE DESCRIPTION	The ROMED surgeon's gloves are made of natural rubber, sterile and powdered with USP absorbable dusting powder. E.P. content is less than 100 µg/gm. Surgeon's gloves are in conformity with ASTM D3577-00a standard.	
INDICATIONS FOR USE	The ROMED surgeon's sterile powdered gloves is a single use disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	
TESTING	Shelf life, primary skin irritation test, guinea pig maximization test, toxicity	
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The ROMED surgeon's sterile and powderd gloves are substantially equivalent to the predicate devices in intended use and principles of operation	
CONCLUSION	Based on the information presented, Van Oostveen Medical B.V. believes that the proposed surgeon's gloves meet the minimum requirements that are considered acceptable for its intended use and is substantially equivalent to other currently marketed gloves	

IV DEVICE DESCRIPTION

The ROMED surgeon's gloves are made of natural rubber, sterile and powdered.
The ROMED surgeon's gloves are powdered with absorbable dusting powder USDP corn starch as the donning lubricant.

The ROMED surgeon's sterile powdered gloves is a single use disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

Ms. Yvonne Zwaartman
Van Oostveen Medical B.V.
Herenweg 269
3648 CH Wilnis
Holland

Re: K023139
Trade/Device Name: Romed Latex Surgical Gloves, Powdered, Sterile
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: October 9, 2003
Received: October 14, 2003

Dear Ms. Zwaartman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K023139

Device name: surgeon's gloves, sterile, powdered

Indications for use:

The ROMED surgeon sterile powdered gloves is a single use disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Patricia D. Cohen, Branch Chief, DMCB
10/21/03

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023139

(PLEASE DO NOW WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use _____
(Per 21 CFR 801.109)

Over-The-Counter Use _____

(Optional Format 1-2-96)